NDA 20-165/S-019

GlaxoSmithKline Consumer Healthcare
Attention: David Schifkovitz
Director, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054-3884

08 JUN 2001

Dear Mr. Schifkovitz:

Please refer to your supplemental new drug application dated July 28, 2000 received July 31, 2000 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Clear NicoDerm CQ® (nicotine transdermal system).

This supplemental new drug application provides for revised labeling changes to be made within 180 days or the next printing based on the approval letter dated February 16, 2000 for Clear NicoDerm CQ®.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (immediate container and carton labels) submitted July 28, 2000 and must be formatted in accordance with the requirements of 21 CFR 201.66. These revisions are terms of the approval of this application.

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-165." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Daniel P. Keravich, M.S., M.B.A., Regulatory Health Project Manager, at 301-827-2248.

Sincerely,

Linda M. Katz, M.D., M.P.H.
Deputy Director
Division of Over-The-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research